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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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David Wallach

WALLACH=25

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EXAMINER

QIAN, CELINE X

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/671,687	Applicant(s) WALLACH ET AL.	
	Examiner CELINE X. QIAN	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,20-24,38,42,44-46 and 48-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44-46 is/are allowed.
- 6) ☐ Claim(s) 2,20-24,38,42 and 48-50 is/are rejected.
- 7) ☐ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/646,403.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 2, 3, 20-24, 38, 42, 44-50 are pending in the application.

This office action is in response to the Amendment filed on 12/19/07.

Response to Amendment

The finality of the office action mailed on 5/4/07 has been withdrawn.

The rejection of claims 2, 20-24, 38, 40, 42, 43, 47-50 under 35 U.S.C. 112 2nd paragraph has been withdrawn light of the amendment.

Claims 2, 20-24, 38, 42, 48-50 are rejected under 35 U.S.C. 112 1st paragraph for reason discussed below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 20-24, 38, 42, 48-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to isolated proteins capable of binding to tumor necrosis factor receptor-associated 2 protein (TRAF-2), wherein said proteins comprises a polypeptide of SEQ ID NO: 3, or a variant that has not more than 10 amino acid changes from the amino acid sequence of SEQ ID NO:3. The claims are further drawn to proteins capable of binding to

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TRAF-2 and which have no more than 5 (claim 48) amino acid changes from the amino acid sequence of SEQ ID NO: 3. The claims are further drawn to molecules having the binding portion of an antibody capable of binding to such isolated proteins. The claims encompass any protein, wherein at least a portion of the protein has 5 or 10 amino acid changes from the amino acid sequence of SEQ ID NO: 3. The claims do not provide any structural information with regard to sequences with 5 or 10 amino acid changes from SEQ ID NO: 3 capable of binding to TRAF-2 or to components of the NF-KB complex selected from IKAP, IKK-alpha, IKK-beta, IKK-gamma and NIK (claim 38). Thus, the rejected claims comprise a set of nucleic acid sequences that are defined by the function of the encoded protein.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any combination thereof. The specification describes a NAP protein of SEQ ID NO: 3 that was identified in a yeast two-hybrid assay and is capable of binding NEMO and TRAF-2 (see, e.g., page 99, Table 2). No description is provided of a single variant (truncated, fused to another protein or protein domain, mutated by insertion, mutated by deletion, mutated by amino acid substitution or otherwise) that has no more than 5 or 10 amino acid from SEQ ID NO: 3, including conservative substitution (claims 49 and 50). No description is provided of a variant of SEQ ID NO: 3 of any kind that is capable of binding to TRAF-2 or to an NF-KB complex. Applicant claims the proteins and antibodies capable of binding to such proteins by function only (i.e., their ability to bind to TRAF-2 and the NF-KB regulatory complex), without any disclosed

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or known correlation between the elements and their function. The claims read on any protein variant that can bind to TRAF-2 as long as the protein has no more than 5 or 10 amino acid change from SEQ ID NO: 3, but the specification only describes one specific embodiment, NAP as encoded SEQ ID NO: 3. Furthermore, the specification does not provide a structural analysis of NAP to identify the relevant structural features that are required for binding activity. For example, is there a specific domain that can be found in multiple proteins that would allow the skilled artisan to envision the proteins that are claimed? Are there multiple proteins that are structurally divergent that can bind to TRAF-2 or to the NF-KB complex protein recited? The skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification because the specification only discloses a single protein, rather than a representative number of species within the genus as claimed, and the specification does not indicate the relevant structural features that are required for the interaction to take place. Even if one accepts that the example described in the specification meets the claim limitations of the rejected claims with regard to structure and function, the example is only representative of one amino acid sequence capable of binding TRAF-2. It is impossible to extrapolate from the example described herein those amino acid molecules that would necessarily meet the structural/functional characteristics of the rejected claims. The prior art does not appear to offset the deficiencies of the instant specification in that it does not describe a set of genes or proteins that bind to TRAF-2 or NF-KB complexes and comprises a variant of SEQ ID NO: 3 that has at least 5 or 10 amino acid changes including deletion, insertion, substitution. There is no description of the relevant structural features that are required for an interaction between TRAF-2 and NAP. There is no identification of a domain that has the capacity to bind to TRAF2. Thus,

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the skilled artisan cannot rely on the prior art to envision a sufficient number of embodiments of the instant invention to see that Applicant was in possession of the claimed genus. Given the large genus of amino acid molecules encompassed by the rejected claims (the change can occur at any place within the 625 amino acid sequence), and given the limited description provided by the prior art and specification with regard to the claimed amino acid sequences, the skilled artisan would not have been able to describe the broadly claimed genus of NAP sequences that bind to TRAF-2 and to the recited components of the NF-KB complex listed in claim 38. Thus, there is no structural/functional basis provided by the prior art or instant specification for one of skill in the art to envision those amino acid sequences, aside from SEQ ID NO: 3, that satisfy the functional limitations of the claims. Therefore, the skilled artisan would have reasonably concluded Applicant was not in possession of the claimed invention.

Conclusion

Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 44-46 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Celine X Qian Ph.D./
Primary Examiner, Art Unit 1636